

BIOETHICS BULLETIN

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Congratulations on your position as Chief of the Department of Bioethics! What motivated you to apply for the position?

Thank you. I've been here since the beginning of the department and so I'm very committed to it. It's a great place to work, with a lot of very smart and thoughtful people, a very productive group, and collaborative. I think we also provide a wonderful service to the NIH. We have the consult service, which is critical, but we also provide consultation to people at the NIH who don't come through the consult service. We sit on IRBs, DSMBs, advisory committees, and committees of all kinds. The excellence we have in our service, our research, and our training program are reasons we should be very proud of this department. I would like to continue to try to make them as excellent as possible.

What direction do you hope to take the Department in the future?

I'd like to bring more science to the Department. You can't make decisions or provide consultation or conduct worthwhile research projects unless you understand the basics of what you're dealing with. One of the areas that we could and should be leaders in is the intersection

Christine Grady Appointed Department Chief

between research and care because it's changing. There are many opportunities for doing research based on data, samples, and interventions that are done in a clinical context. People are beginning to recognize that, but it raises a whole new pool of ethical issues. We need a foundation of methodology: scientific methodologies and clinical trial designs. Steve Pearson's work on technology assessment, cost-effectiveness, comparative effectiveness and patient-centered outcomes is the direction that research is going in. We need to be right there on the ethical issues that are involved.

There are exciting scientific areas to work in: the whole genome and emerging technologies including stem cells. Genetics is not only moving fast, but the contribution that Sara and Ben have made has been very important and valued by the rest of the community. We can do a similar thing in neuroscience, or "neuroethics." We could collaborate with people at NIH, and capitalize on some of that leading science.

That's a lot. Do you ever worry about us getting stretched too thin?

Yes, I do. I don't think the Department will grow much because of the budget. We have some interesting models that share people with Fogarty or NHGRI (National Human Genome Research Institute). I would love to see that model expanded. That may be the best way we can grow: by collaborative relationships with other NIH entities that are willing to support part of a person or part of a program in some way.



What challenges do you foresee?

The major one in the short term is going to be budget cuts. The NIH is experiencing budget cuts across the board and we're going to have to be creative in using the resources we already have. Also (and this may be of interest to alumni), there is an effort to optimize the bioethics effort across the NIH, especially the extramural portfolio. I think that should happen. Currently the NIH funds bioethics research through its various institutes, but there's no central coordination. I've been working with others to try to create political will for a central program that would coordinate across institutes. We should be integrally involved in that effort. We certainly stand ready to make it happen in any way that we can.

What can alumni expect from a Department led by Chief Grady?

We'll still have tea. And lots of food! I'm running a contest to coin a new description of our culture to replace "Combative Collegiality." It was a defining era and now we're in a new era.

Interview with Joe Millum on *Global Justice and Bioethics*

You and Zeke edited and contributed to [an anthology](#) that recently came out. What in particular interests you about the combination of global justice and bioethics?

According to one reading of the history of bioethics, bioethics has primarily focused on relationships—the doctor-patient relationship or the researcher-subject relationship—and focused much less on systems and institutions. But recently, people have become more concerned about the institutional context in which people operate: what is it that doctors are doing, and how does that relate to the hospital or the health care system they're working within?

Further, the fact that health care and health research have become international means that concerns about bioethics become international. And when you have researchers that are going from very wealthy to very poor countries and they ask questions about the differences in the health care systems and access, e.g. *why have these people waited for three days before bringing their child to the clinic?*, they're reasoning that way because of the context they're used to being in. In the US, if a child has a really severe fever, obviously the parents go to the doctor immediately. If you're somewhere where that doesn't happen, you have to ask *why?* Well it costs money, and you have to take a day off work because it takes time to travel, and you're not sure if the child will get treated, and so on.

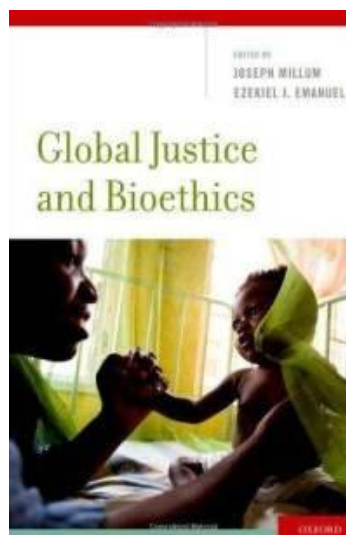
The two trends go together—health workers and researchers have moved outside of nations and we're more concerned with thinking about systems and institutions. The justice angle then becomes obvious.

Does the book fill a gap in the literature?

I think so. A lot of what's written on international bioethics doesn't draw on political theory as much as it could. A lot of the work on political theory is work on ideal theory, not applied specifically to real world problems. These are gross generalizations, but the desire is for work with the analytical rigor and foundational thinking from political philosophy and with focus on the practical concerns and understanding of applied context from bioethics work. People who can bridge this gap are doing something useful.

Who is the intended audience of the book?

Academically, it's aimed at both political theorists and bioethicists. The hope was to feed in both directions, much like the fellowship program here. You want to



take in people who are rigorously trained in, say, philosophy and you want to expose them to the problems in bioethics with the hope that you get better work in bioethics and they go back to philosophy saying, "here are these interesting questions that people other than philosophers are working on. We should care about this." We also hope it'll have interest for a wider audience—students who are interested in global health, for example. They're often quite motivated by feelings of injustice, but might not have thought too deeply about it.

You wrote the first chapter, "Global Bioethics and Political Theory." What do you argue for?

That chapter argues that we should care about questions of political theory when answering bioethics questions. There's a view in global justice called *cosmopolitanism*, which roughly says that borders or nation states are not normatively significant. And then there's a view I've labeled *statism* that says that the boundaries of states are what determines who counts from the standpoint of justice. There's a tendency in bioethics to ignore the difference between those positions. But they make a big difference. The *brain drain* is one example. Everywhere in the world there is demand for more doctors and nurses. You can pay doctors more in developed countries, and you get targeted recruiting of doctors from developing nations. This obviously has an effect on the country from which people come. Countries in Sub-Saharan Africa have both greatest disease and lowest number of personnel. To some, this is an injustice. From another viewpoint, you wonder, do you want to restrict the freedom of people to immigrate to a country that wants them? How we resolve these questions depends on whether we're cosmopolitan or statist. If you're a statist, then the UK, for instance, doesn't owe anything to another state or the people in that state with whom it negotiates. It can do more or less what it wants to with regard to recruiting them. If you're a cosmopolitan, then the UK has the same duty to assist people in these other countries as it does in its own. I parenthetically argue that not only would cosmopolitanism forbid the UK from poaching people from Ghana to work in the National Health Service, but really it should be training its own people to treat people in Ghana. We should treat these populations the same. In short, it matters whether you're a statist or a cosmopolitan.

Electives Expand Field Opportunities for Second-Year Fellows

Over the last several years, fellows have advocated for expanding the number and types of “field opportunities” available during their time at NIH. Based on this feedback, Christine decided to pilot an “electives” program: Second-year fellows now have the opportunity to pursue bioethics-related placements that further their career goals by tailoring the fellowship to particular areas of bioethics that interest them. Alumni have been instrumental in helping current fellows find opportunities in their fields of interest. In the three years since the elective program was implemented, fellows have chosen to partake in lab research, intern at global health organizations, shadow the Spiritual Ministry Department at the Clinical Center, volunteer at public health NGOs, and work in health policy on Capitol Hill. The Department hopes that the extensive alumni network can help fellows identify elective opportunities in their diverse fields of interest.

Greer Donley ('11), who is currently pursuing a JD-MPH at the University of Michigan, interned at the Pan American Health Organization (PAHO) after reaching out to **Carla Saenz** ('10) who is currently the Bioethics Regional Advisor. “I had always known about PAHO and liked the organization, so when I found that Carla was transitioning to PAHO after the fellowship, we started talking.” There she examined the reasons research proposals were rejected by PAHO’s ethical review committee. “I was given access to the files on every proposal that had been submitted since the Committee adopted their online system.”

At PAHO, Greer was able to apply what she had learned during her first year in the Bioethics fellowship. “I went through all the decisions the Committee sent out – accept, reject, why – and tried to fit it into the Emanuel, Wendler, Grady framework of seven requirements for ethical research. I basically found that almost every proposal that had been rejected outright had problems with methodology, [such as] huge problems with the statistics of the study.”

Kacey Wulff ('11) was interested in global development and chose to work at the Office of Global AIDS Coordinator (OGAC). “I really loved the comparative effectiveness project I was doing with Frank and Steve, but I also had this parallel interest in global health. I wanted to use my elective as an opportunity to dive into that.”



Carla Saenz was a second-year post-doc when Greer Donley was a first-year pre-doc. Carla (who herself got started at PAHO through her second-year elective) later helped Greer set up a PAHO internship.

Like many fellows’ placements, Kacey’s elective at OGAC took the shape of a discrete research project. She analyzed the results of surveys examining how Global Fund grantees experienced multilateral diplomacy on-the-ground. “There’s a lot of monetary evaluation for distribution and utilization of funds, but [OGAC] was really curious about how all these different representatives and stakeholders on the ground are working together. What is the collaboration experience like in the communities? We asked them: are you duplicating efforts? Are you setting goals together? Have you been to consortium meetings? Are you comparing results? It was a cool project.”

Electives can be an opportunity for fellows to see bioethics in action. For Greer, reviewing protocols for PAHO was very different from observing IRB meetings at NIH. “What was really cool for me was to see what proposals really look like, especially in the field, and especially in a different context from the NIH. A lot of public health research is underfunded. It’s often a doctor who’s seeing something on the ground and wants to test it to see if it’s actually helping people.”

Kacey gained a new, more nuanced understanding of global development thanks to her elective at OGAC. “I’d spent a lot of brainpower thinking from a philosophy perspective about what the ‘ought questions’ are in development, but I didn’t really understand what the practical limitations were. I think it’s interesting to figure out, given the world as it is, what can be done. An elective is an opportunity for exposure that you think is going to help you become a better thinker and researcher. That’s what I really felt like I got out of it.”

Interview with Marion Danis on *Research Ethics Consultation: A Casebook*

[The Casebook](#) was published with several other members of the Department. Tell us about it.

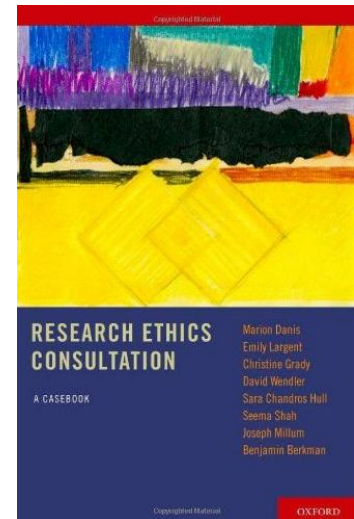
It's a casebook of research ethics consultations that we've done here at the Clinical Center derived from over a decade of experiences recorded in our database of over 900 consults. We were motivated to do this because our experience is fairly novel. Most ethics consultants had been working in the health care arena. The Clinical Center provides this unique setting of being in a hospital where only research participants are enrolled. We have the opportunity to address ethical issues, dilemmas and conflicts around the conduct of research. We think it is useful for other people doing research to see what our experience has been.

Does the book fill a gap in the existing consult literature?

There is nothing else quite like it. There are textbooks on research ethics and articles on individual issues. But a lot of people who are trained in ethics and are involved in the ethics of human subject research have IRBs as the venue for thinking about the ethics of research. IRBs are regulatory venues, and ethics consultants who have worked in health care ethics have the skills for thinking and helping practitioners think through ethical issues in an environment that's not particularly regulatory. There's this whole new interest in inculcating ethical thought about research. In running a research ethics consultation service you can engender that kind of skill without having this regulatory atmosphere.

Who is the intended audience of the book?

It could be investigators, teachers of clinical scientists, or IRBs who want to see the kind of issues that we've encountered. It's potentially inclusive of nonprofessionals in the same way that clinical ethics consultation is useful for leveling the playing field and allowing for patients and families to have a dialogue with clinicians about some of the ethical issues they face: research ethics consultation is a place where we encourage research participants and surrogates to ask questions if they have any problems. One part of the book I hope people will focus on is the Introduction where we describe how we work and the philosophy of our service. That's a really approachable part of the book. In terms of audience, people who are in leadership positions in research entities and organizations conducting research might find it interesting to read the book because it shows the role that research ethics consultation might play in facilitating the ethical conduct of research in their organizations.



How were the cases selected for the book?

With the help of a summer intern, we combed through the 900 cases in the database and assigned them categories. These categories relate to the sequential steps involved in research. First you think about conceptualizing a project, then writing a protocol, submitting for review, recruitment, enrollment, and collecting data. Then you analyze the data and report. You might encounter ethical questions at any point along the way. So those elements of the research process were the basis for our categories. We selected from each category the most interesting consults. We aimed to have about 50 cases in the book. The final step in selection was getting the requestors to approve the anonymized cases. When you say to people "the question you brought to our attention is useful to other people," they're receptive because you're making them a part of ethics teaching and not just a subject.

Do you think there will be a second edition?

I hope that the next development will grow out of the national database that we're participating in with research ethics consultation services in 11 academic medical centers, all funded through Clinical and Translational Science Awards. This will facilitate the development of research ethics consultations as an endeavor that's similar to the evolution of health care ethics consultation. It's not clear at the get go what the one right way is, if any, to organize this kind of service. If you're funded to provide ethics support to researchers, should you mandate that everyone ask for a consult? Or should you organize your service so that everyone knows about you and you provide an educational role? It will be interesting to see how the different kinds of consults arise in institutions that have different strategies for offering them. There are lots of ethical issues that we don't cover on our service, such as animal research ethics or private sector research. Some of these other institutions may fill those gaps.

The Alumni Corner

Class of 1999

After 21 years of teaching law in Cleveland, **Dena Davis** has moved to Lehigh University, where she has all sorts of interdisciplinary mandates and also teaches undergrads. She writes, "Undergrads are much like stem cells: undifferentiated, totipotent, and they think they're immortal." Dena says she is having fun, and also enjoying the proximity to NYC, Philadelphia, and Washington."

Ingrid Burger is finishing up residency in Diagnostic Radiology at UCSF this July and starting a one-year fellowship in ultrasound and breast imaging at UCSF. She writes, "I'm very much looking forward to the end of my training! Since being on the west coast, I've enjoyed more time with family and exploring the outdoors, taking trips to Yosemite, Point Reyes, Big Sur, Napa, and Hawaii."

Class of 2001

Heidi Forster Gertner continues to practice law at the U.S. Food and Drug Administration where she has worked on human subject protection issues and drug regulation for the past 11 years. She lives in Bethesda with her husband and three kids. Feel free to contact her at heidigertner@yahoo.com.

Stephen Green retired from clinical practice last spring and now lives in New York City. He is still a member of the Georgetown faculty and is currently a member of the ethics committee of Memorial Sloan Kettering Hospital. He can be reached at: greenm1@georgetown.edu.

Class of 2002

Maria Merritt and her husband Stuart Chaitkin recently adopted a 4-year-old cat named Slinky from the Maryland SPCA. Slinky is black with a white blaze, chest, and paws and enjoys a carefree life dedicated to playing and sleeping.

Gopal Sreenivasan and **Jennie Hawkins** continue to be happy at Duke, where they are both split between philosophy and the Trent Center for Bioethics in the medical school. Janaki and Ambika (3.5 & 1.5, pictured) are professional rascals and very good at lounging.



Class of 2003

Christine Pace finished residency in Internal Medicine/Primary Care at Brigham and Women's Hospital in 2010 and is now finishing a fellowship in Addiction Medicine at Boston Medical Center. Next year she will stay on as faculty at BMC, doing clinical, programmatic and policy work around the integration of primary medical care with substance abuse services, which she finds endlessly interesting. Her biggest news is that she and her husband are expecting their first baby any day now!

In the past year, **Samia Hurst** completed a four year stint as president of the Swiss Society for Biomedical Ethics. She is still Swiss National Science Foundation professor in Geneva, and this grant has allowed her to hire some pretty amazing people. Unfortunately, in the past few years she has not been able to import the NIH tea in Geneva, but have been very successful with a version involving morning coffee. One more thing: Contact her if you pass through Geneva!

Since leaving DC, **Elizabeth Wahl** is STILL in New Haven. She has finished med school and residency and is a fellow in Rheumatology: "I love it - clinically interesting, both personally and intellectually fulfilling. Also exhausting, but that's first year of fellowship for you." Her husband is an MD/PhD student (who just defended, yahoo) so he will go through the match next year.

Class of 2004

Nir Eyal has recently married. His better half's name is Leah Price. She teaches English Literature at Harvard, and they report being very happy together.

Class of 2006

Larry Temkin's book [*Rethinking the Good: Moral Ideals and the Nature of Practical Reasoning*](#), which he worked on during his year at the NIH, has recently been released by Oxford University Press (January, 2012).

Samia Hurst (2003) and NIH Visiting Professors **Thomas Pogge** (2004), **Gopal Sreenivasan** (2002), and **Larry Temkin** (2006) were four of the six main speakers at an April 2012 conference in Montreal on *Justice in Health: Trade-offs and Conflicting Values*, sponsored by the Montreal Health Equity Research Collaboration.

Class of 2007

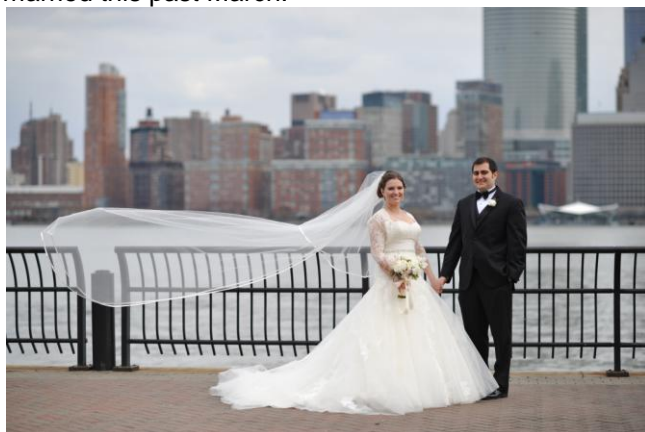
Jon Tilburt is currently working at the Mayo Clinic. He recently got an R01 on communication about CAM in Cancer and a Greenwall Faculty Scholar Award on Ethical Issues in Implementing Shared Decision Making in the Wake of US Healthcare Reform. He has stayed connected to the department with intermittent work with Frank on placebo issues and work with Marion on stewardship/cost-containment issues. He writes, "Our family now includes 4 kids and our same old dog who is now 13. With global warming, Minnesota has turned about to be a pleasant and mild place to live."

Since returning to Sri Lanka in 2007, **Vajira Dissanayake** has been working to improve the standard of research ethics review in the country. He has also been working with the Forum for Ethical Review Committees in Asia and the Western Pacific (FERCAP) as a member of its Steering Committee. This year he took over as the President of the Sri Lanka Medical Association and is in the process of making arrangements to host the Annual International Conference of FERCAP in Colombo in November 2012.

Sumeeta Varma has recently graduated from Washington University School of Medicine. She received her Doctor of Medicine and Master of Science in Clinical Investigation on May 18.

Class of 2009

Rebecca Wolitz and her fiancé Greg (below) were married this past March.



Collin O'Neil is at the Center for Bioethics at NYU, keeping very busy with teaching, writing, and presenting, but still finding time for entertainment, restaurants, music, and a new interest, live storytelling (listening not telling). He'll be teaching a new course this summer on Justice and Health, and then teaching courses on Bioethics, Research Ethics, and Medical

Ethics again during the regular school year. Collin's wife Mercedes is enjoying her job at the Lasker Foundation. They award prizes to medical researchers.

Ben Sachs will be starting a new job in September: lecturer in the Department of Moral Philosophy at the University of St. Andrews.

Class of 2010

Carla Saenz is in charge of the Regional Program on Bioethics of the Pan American Health Organization, which is the World Health Organization's Regional Office for the Americas in Washington DC. The Regional Program supports and strengthens the work on bioethics in Latin America and the Caribbean, where they team up with various organizations and academic institutions in the Americas and the rest of the world. Don't hesitate to email me if you're interested in the work on bioethics in Latin America and the Caribbean. Contact info: saenzcar@paho.org and bioethics@paho.org

Chiara Lepora is currently back working with MSF based in Dubai and travelling extensively in the region to: Yemen, Iraq, Libya, Qatar, Saudi Arabia, etc. She writes, "Every day, I encounter and try to answer the types of questions I had the opportunity to explore at the NIH: Can one treat Al-Qaida fighters without necessarily agreeing with what they do after their treatment? Is it ethical to provide surgical equipment to doctors working in clandestine structures if they are inappropriately trained and organized? How can acceptable social behaviors be promoted and demanded from traumatized patients? Every day, I thank the department for providing me with frames of reference in addressing these problems."

Emily Largent writes: "Introducing our little girl: Meara Flannery Donovan. She was born June 26th, and we just brought her home today. We couldn't be happier -- suffice it to say that we're completely smitten!"



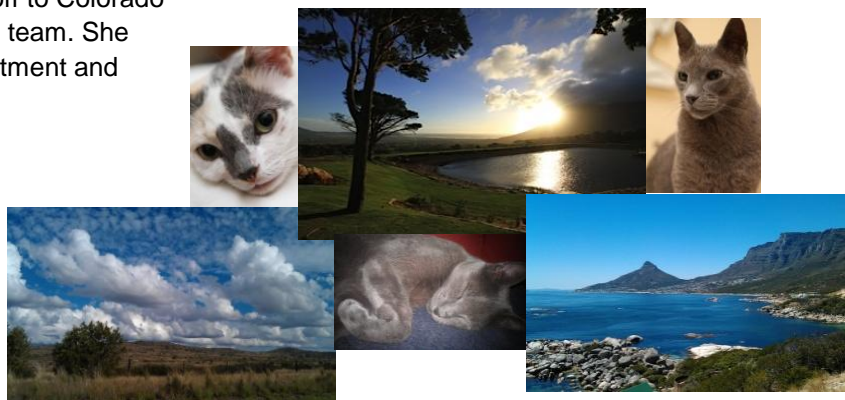
Class of 2011

Greer Donley completed her first year of law school at the University of Michigan, and her paper with Ben Berkman and Sara Hull on prenatal whole genome sequencing was recently accepted in *The Hastings Center Report*. She is in DC this summer at the National Women's Law Center in the Health Law and Reproductive Rights Division. She is conducting research on the Affordable Care Act and its impact on poor women. Super pumped!

Michael Tal was appointed as of March 1st to be the chair of the University Committee for the Use of Human Subjects in Research Institutional Review Board, which is different from the committee that deals with clinical trials. He hopes to meet those of you who are going to participate in the ASBH meeting in DC this fall.

This spring, **Kacey Wulff** graduated from the MPH program at Johns Hopkins. She is off to Colorado to work with the Women for Obama team. She says hello to everyone in the Department and "Make sure to vote!"

On 1st of June **Nicola Barsdorf** started work as ARESA (Advancing Research Ethics training in Southern Africa) programme coordinator in the Centre for Medical Ethics and Law at Stellenbosch University. She is also working with the HIV AIDS Vaccine Ethics Group (HAVEG) at the University of KwaZulu-Natal on a Wellcome Trust funded empirical study exploring care and prevention practices in HIV vaccine trials in South Africa. She writes, "On a more personal note, we have three recent additions to our family: our two Russian blues, Sacha and Vladilen, and a very "special" rescue kitty, Dafney (see below). It has taken me a while to settle here in Cape Town, but I really am beginning to fall in love with the city, and after a somewhat lengthy adjustment period, I feel at home again. I am hoping that these pictures will inspire some visits to our beautiful country. Come and visit, I would love to host you!"



Announcements

- Our Alumni Newsletter will be published annually. If you would like to include an update in next year's newsletter, please email Becky Chen at bchen@cc.nih.gov. Updates might include any of the following: personal life happenings, publications, new professional involvements or activities, or anything you'd like to share with the current and former department members.
- We also have an alumni listserv to share relevant news articles, job opportunities, and conference announcements. If you are not already on the listserv and would like to join, contact Becky at bchen@cc.nih.gov. To post to the listserv, send an email to bioethics-alumni@googlegroups.com and it will go out to the 100+ members on the list.